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The FDA Just Quietly Gutted Protections for Human Subjects in Research

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From *Newsweek*: "Late last year, the U.S. Food and Drug Administration (FDA) quietly introduced a regulation that may be one of the most important shifts in how non-profit and for-profit U.S. institutions, both at home and abroad, conduct future medical and public health research. It represents an erosion of personal medical choice and threatens to undermine the public's trust in scientific investigations in biomedicine.

A bedrock of ethical research design is the universal requirement of informed consent for any medical procedure, treatment, or intervention. Researchers must provide information to possible participants, without pressure or coercion, to decide whether the risks are worth the potential benefit of an intervention. The FDA's exceptions, until recently, are historically reserved for people who are incapacitated or for urgent, life-threatening emergencies.

These measures have generally been strengthened since the Nuremberg Trials, formally adopted across the U.S. government through the institutional review board (IRB) system . . .

At its core, the new FDA rule change allows any IRB to broadly assume the FDA's own exemption power, dubiously granted under the 21st Century Cures Act of 2016, to grant exemptions to informed consent requirements based on 'minimal risk.' Based on vague guidelines, it effectively gives thousands of IRB committees the unilateral ability to determine that researchers need not obtain true informed consent from research participants.

This new power applies to the IRBs housed at clinical research organizations, universities large and small, pharma companies, and multi-billion dollar corporations that provide IRB services to research groups."

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